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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,314	09/19/2003	James J. Cali	02-482-B	6198

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EXAMINER

PAK, YONG D

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/665,314	Applicant(s) CALI ET AL.	
	Examiner Yong D. Pak	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-167 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-167 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-167 are pending and are subject to restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 111-115, 143 and 158-160, drawn to a method for measuring the activity of a cytochrome P450 enzyme *in vitro*, classified in class 435, subclass 25.
- II. Claims 8-17, 111-115, 144-147 and 158-160, drawn to a method for measuring the activity of a cytochrome P450 enzyme in a cell, classified in class 435, subclass 243.
- III. Claims 18-28, 111-115, 148 and 158-160, drawn to a method for measuring the activity of a cytochrome P450 enzyme in a tissue, classified in class 435, subclass 1.1.
- IV. Claims 29-30, 149 and 158-160, drawn to a method for measuring the activity of a cytochrome P450 enzyme in an animal, classified in class 800, subclass 8.
- V. Claims 31-40, 66-75, 111-115, 150, 154 and 158-160, drawn to a method for screening a compound for its effect on cytochrome P450 activity *in vitro*, classified in class 435, subclass 25.

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- VI. Claims 41-49, 76-88, 111-115, 151, 155, 158-160, drawn to a method for screening a compound for its effect on cytochrome P450 activity in a cell, classified in class 435, subclass 243.
- VII. Claims 50-58, 89-102, 111-115, 152, 156 and 158-160, drawn to a method for screening a compound for its effect on cytochrome P450 activity in a tissue, classified in class 435, subclass 1.1.
- VIII. Claims 59-65, 103-111-115, 153, 157 and 158-160, drawn to a method for screening a compound for its effect on cytochrome P450 activity, classified in class 800, subclass 8.
- IX. Claims 116-131, drawn to a kit for determining the effect of a substance on cytochrome P450 activity, wherein the kit comprises a luminogenic molecule and a pro-substrate of luciferase, classified in class 252, subclass 700.
- X. Claims 132-142, drawn to a composition comprising a luciferin derivative, classified in class 546, subclass 118.
- XI. Claims 161-167, drawn to a method for enhancing the stability of a luminescent signal generated by a luciferase reaction mixture by contacting a luciferase with a luciferase inhibitor, classified in class 435, subclass 189.

The inventions are distinct, each from the other because of the following reasons:

The products groups IX-X are patentably distinct inventions because group IX is drawn to a kit comprising a luminogenic molecule and a pro-substrate for luciferase and

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group X is drawn to a composition comprising luciferin derivative. The products have different structure and function different. Furthermore, searching the inventions of groups IX-X together would impose a serious search burden. In the instant case, the search of a kit comprising a luminogenic molecule and a pro-substrate and a composition comprising luciferin derivative are not co-extensive. The inventions of Groups IX-X have a separate status in the art as shown by their different classifications.

Inventions I-VIII and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different function or different effects. (MPEP 806.04, 808.01). The instant specification does not disclose that these methods would be used together. The method of using a cytochrome P450 enzyme (groups I-VII) and the method of using a luciferase (group XI) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Further, an *in vitro* method (groups I and V), methods using a cell (groups II and VI), methods using a tissue (groups III and VII) and methods of using a transgenic animal (groups IV and VIII) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Therefore, the methods of groups I-VIII and method of group XI are divergent in materials and steps. Further, the distinct steps and products require separate and distinct searches. As such, it would be burdensome to search groups I-VIII and XI together.

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Inventions I and V, Inventions II and VI, Inventions III and VII and Inventions IV and VIII are unrelated because the specification does not disclose that these methods would be used together. The methods are divergent in steps and have different modes of operation. Each invention performs this function using structurally and functionally divergent material. Further, the distinct steps require separate and distinct searches. As such, it would be burdensome to search groups I-VIII together.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species: luciferin derivatives and coelenterazine derivatives. The species are independent or distinct because: each of the possible luciferin derivatives and coelenterazine derivatives having the generic formula recited in claims 112, 113, 126, 128, 135 and 158 have different structure and function.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 111-115, 125-129, 132-135, 140-160 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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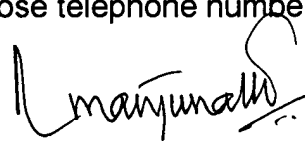
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652



Rao Manjunath
Primary Patent Examiner 1652